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10/553,669

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Daniel H.S. Lee

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EXAMINER

HA, JULIE

ART UNIT

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1654

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/553,669	<b>Applicant(s)</b> LEE ET AL.	
	<b>Examiner</b> JULIE HA	<b>Art Unit</b> 1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 42-60 is/are pending in the application.
- 4a) Of the above claim(s) 48 and 57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 42-47, 49-56 and 58-60 is/are rejected.
- 7) ☒ Claim(s) 49 and 58 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Response to After final rejection filed on April 30, 2009 is acknowledged. No claim amendment has been filed. Upon further consideration, the finality sent out on January 30, 2009 is withdrawn, and the case is hereby reopened. Claims 1-41 and 61 are cancelled. Claims 42-60 are pending in this application. A search was conducted on the elected species, SEQ ID NO: 3, and a prior art was found. Claims 48 and 57 remain withdrawn from further consideration as being drawn to nonelected species. **Claims 42-47, 49-56 and 58-60 are examined on the merits in this office action.**

### ***Withdrawn Rejections***

1. Rejection of claims 42-47, 49-56 and 58-60 under 35 U.S.C. 112, second paragraph, as being indefinite, is hereby withdrawn in view of Applicant's arguments.
2. Rejection of claims 42-45, 47, 51-53 and 60 under 35 U.S.C. 103(a) as being unpatentable over Strittmatter (US Patent No. 7,119,165) in view of Strittmatter SM (J. Mol. Neurosci., 2002, 19(1/2): 117-121, filed with IDS, NPL33), is hereby withdrawn in view of Applicant's arguments.

New Rejections follows below.

### ***New Objections***

3. Claims 42, 49, 56 and 58 are objected to for the following reasons:

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4. Claims 42 and 56 recite, "...wherein the soluble Nogo receptor-1 polypeptide is soluble form of a mammalian NgR1." The "NgR1" needs to be spelled out at the first occurrence. Applicant is required to correct these errors.

5. Claim 49 is dependent on claim 48, which was withdrawn because it does not read on the elected species. Claim 48 recites, "...amino acids 26 to 310 of human NgR1 (SEQ ID NO:3) with up to ten conservative amino acid substitutions..." This is interpreted as having at least 1 and up to 10 conservative substitutions. The specification did not define what "up to ten conservative substitutions" is. Therefore, since at least 1 and up to 10 conservative substitutions is different from SEQ ID NO: 3, claim 48 does not read on the elected species, SEQ ID NO: 3, therefore, withdrawn from consideration. Since claim 49 depends from a withdrawn claim, claim 49 is objected to.

6. Claim 58 is dependent on claim 57, which was withdrawn because it does not read on the elected species. Claim 57 recites, "...amino acids 26 to 310 of human NgR1 (SEQ ID NO:3) with up to ten conservative amino acid substitutions..." This is interpreted as having at least 1 and up to 10 conservative substitutions. The specification did not define what "up to ten conservative substitutions" is. Therefore, since at least 1 and up to 10 conservative substitutions is different from SEQ ID NO: 3, claim 57 does not read on the elected species, SEQ ID NO: 3, therefore, withdrawn from consideration. Since claim 58 depends from a withdrawn claim, claim 58 is objected to.

***New Rejection***

***35 U.S.C. 112, 2<sup>nd</sup>***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 50 and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 50 recites, "wherein the soluble form of a mammalian NgR1 further comprises a fusion moiety." It is unclear what is encompassed within "a fusion moiety". The instant specification discloses that "the fusion moiety is an immunoglobulin moiety....the immunoglobulin moiety is an Fc moiety" (see paragraph [0008] of instant specification US 2007/0065429). The dictionary defines a moiety as "an indefinite portion, part, or share" (see p. 1, from <http://dictionary.reference.com/browse/moiety>, enclosed). Therefore, a moiety can be any part of an immunoglobulin or Fc. Therefore, it is unclear what components are encompassed within the term "moiety".

10. Claim 59 recites, "wherein the soluble form of a mammalian NgR1 further comprises a fusion moiety." It is unclear what is encompassed within "a fusion moiety". The instant specification discloses that "the fusion moiety is an immunoglobulin moiety....the immunoglobulin moiety is an Fc moiety" (see paragraph [0008] of instant specification US 2007/0065429). The dictionary defines a moiety as "an indefinite portion, part, or share" (see p. 1, from <http://dictionary.reference.com/browse/moiety>,

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enclosed). Therefore, a moiety can be any part of an immunoglobulin or Fc. Therefore, it is unclear what components are encompassed within the term "moiety".

**35 U.S.C. 102**

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 42-47, 49-50, 52-56, 58-59 are rejected under 35 U.S.C. 102(e) as being anticipated by Lee et al (US 2005/0271655 A1, provisional date August 10, 2002 and published on December 8, 2005, filed with IDS).

13. Lee et al teach SEQ ID NO: 7 which comprises the instant SEQ ID NO: 3. The reference teaches that a soluble Nogo receptor-1 polypeptide consisting essentially of a N-terminal domain (NT), 8 leucine rich repeat domains (LRR) and a LRR C-terminal domain (LRRCT) of Nogo receptor-1...a soluble Nogo receptor-1 polypeptide selected from the group consisting of: amino acid residues 26-344 of SEQ ID NO: 6; **amino acid residues 26-310 of SEQ ID NO: 7**; amino acid residues 26-344 of SEQ ID NO: 8; amino acid residues 26-310 of SEQ ID NO: 9; amino acid residues 27-344 of SEQ ID

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NO:8; and amino acid residues 27-310 of SEQ ID NO: 9 (see paragraph [0024]), meeting the limitation of claims 49 and 58. The reference teaches a method of promoting survival of a neuron comprising contacting the neuron with an effective amount of a soluble Nogo receptor-1 polypeptide...the soluble Nogo receptor-1 polypeptide is a fusion protein, e.g., an Fc-fusion protein. In some embodiments, the neuron is in a mammal displaying signs of symptoms of, e.g., multiple sclerosis, ALS, Huntington's disease, Alzheimer's disease, Parkinson's disease...spinal cord injury (see paragraph [0021]), meeting the limitations of claims 42-44, 47, 49-50, 52, 56, and 58-59. Furthermore, the reference teaches that dosage regimens may be adjusted to provide the optimum desired response, a single bolus may be administered...to formulate parenteral compositions in dosage unit form for ease of administration and uniformity of dosage unit (see paragraph [0140]. The reference teaches providing a soluble Nogo receptor-1 polypeptide at or near the site of the neurons (see paragraphs [0145] and [0151] and [0153]), meeting the limitation of claims 46 and 55. The instant claims do not define the patient population. The claims are drawn to a method of reducing the symptoms, not treating the disease. Therefore, anybody being administered the soluble Nogo-receptor polypeptide would necessarily have reduction in A $\beta$  peptide levels. Therefore, the reference meets the limitation of claims 42-47, 49-50, 52-55 and 58-59. Please note, the reference teaches the nonelected species, instant SEQ ID NOS: 4, 5 and 6.

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14. Claims 42-47, 50-56 and 59-60 are rejected under 35 U.S.C. 102(e) as being anticipated by Strittmatter (US 2002/0077295 A1, filed on October 6, 2001 and published on June 20, 2002, filed with IDS).

15. Strittmatter SM teaches the soluble NgR1 polypeptide having 283 amino acid residues (see SEQ ID NO: 55). This peptide sequence is different from the elected sequence SEQ ID NO: 3 in that it is missing the first proline and the last cysteine residues. Since the sequence has the NT domain, eight leucine rich repeats, and an LRRCT (leucine-rich-repeat domain C-terminal of the eight leucine-rich repeats) domain, this meets the limitation of claims 42 and 52. Strittmatter teaches that the soluble NgR1 polypeptide is used for the treatment of central nervous system disease, disorder or injury, and the term CNS includes, altered CNS function resulting from physical trauma to cerebral or spinal chord tissue, viral infection, autoimmune mechanism, genetic mutation and neurodegenerative diseases or disorders (see paragraph [0084]). The reference further teaches that the typical dosage comprises 1 pg/kg to 100mg/kg body weight, preferred dosage for systemic administration comprise 100 ng/kg to 100 mg/kg; preferred dosages for direct administration to a site via microinfusion comprise 1 ng/kg to 1 µg/kg body weight (see paragraph [0178]). Since the range of the dosage encompasses the 0.001 mg/kg to 10 mg/kg range, this meets the limitation of claims 51 and 60. Claims do not define the patient population, therefore, any patient being administered an effective amount of a soluble Nogo receptor-1 polypeptide would inherently reduce the levels of Aβ peptide. The claims are drawn to reducing the symptoms, not the disease, therefore, the reference meets the limitation of



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the claims. The mammalian brain can be an in vitro cell, such as brain or brain tissue cells, or brain biopsy. Furthermore, since the patient population is not defined, the administration of the Nogo-1 polypeptide would necessarily reduce the levels of A $\beta$  peptide in all population. Again, the claims are drawn to reducing a symptom, not a disease. The reference teaches that administration of the Nogo peptide agents may be transplanted to a site spinal cord injury to facilitate axonal growth throughout the injured site (see paragraph [0173]), meeting the limitation of claims 46 and 55. The reference teaches that the agents can be administered via parenteral, subcutaneous, intravenous, intramuscular, intraperitoneal, transdermal, or bucal routes...an agent may be administered locally to a site of injury via microinfusion. Typical sites include, damaged areas of the spinal cord resulting from injury or damage sites in the brain (see paragraph [0177]), meeting the limitations of claims 45 and 54. As evidenced by instant specification, "bolus injection" is an injection of an aqueous solution (see paragraph [0053 of instant specification]). Since the reference teaches the parenteral administration of the Nogo-1 peptide, this reads on claims 45 and 54. The reference teaches 140-AP and AP-Nogo-66 fusion proteins (see paragraph [0061] and Figure 15), meeting the limitation of claims 50 and 59. Therefore, the reference anticipates claims 42-47, 50-56 and 59-60.

16. Claims 42-47, 49-50, 52-56, 58-59 are rejected under 35 U.S.C. 102(a) as being anticipated by Lee et al (US 2005/0271655 A1).

17. The teachings of Lee et al are described, *supra*.

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18. Claims 42-47, 50-56 and 59-60 are rejected under 35 U.S.C. 102(a) as being anticipated by Strittmatter (US 2002/0077295 A1).

19. The teachings of Strittmatter are described, *supra*.

***Rejection-35 U.S.C. 103***

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

21. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

22. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

23. Claims 42-47, 49-56 and 58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al (US 2005/0271655 A1).

24. Lee et al teach SEQ ID NO: 7 which comprises the instant SEQ ID NO: 3. The reference teaches that a soluble Nogo receptor-1 polypeptide consisting essentially of a N-terminal domain (NT), 8 leucine rich repeat domains (LRR) and a LRR C-terminal domain (LRRCT) of Nogo receptor-1...a soluble Nogo receptor-1 polypeptide selected from the group consisting of: amino acid residues 26-344 of SEQ ID NO: 6; **amino acid residues 26-310 of SEQ ID NO: 7**; amino acid residues 26-344 of SEQ ID NO: 8; amino acid residues 26-310 of SEQ ID NO: 9; amino acid residues 27-344 of SEQ ID NO:8; and amino acid residues 27-310 of SEQ ID NO: 9 (see paragraph [0024]), meeting the limitation of claims 49 and 58. The reference teaches a method of promoting survival of a neuron comprising contacting the neuron with an effective amount of a soluble Nogo receptor-1 polypeptide...the soluble Nogo receptor-1 polypeptide is a fusion protein, e.g., an Fc-fusion protein. In some embodiments, the neuron is in a mammal displaying signs of symptoms of, e.g., multiple sclerosis, ALS, Huntington's disease, Alzheimer's disease, Parkinson's disease...spinal cord injury (see paragraph [0021]), meeting the limitations of claims 42-44, 47, 49-50, 52, 56, and 58-59. Furthermore, the reference teaches that dosage regimens may be adjusted to provide the optimum desired response, a single bolus may be administered...to formulate parenteral compositions in dosage unit form for ease of administration and uniformity of

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dosage unit (see paragraph [0140]. The reference teaches providing a soluble Nogo receptor-1 polypeptide at or near the site of the neurons (see paragraphs [0145] and [0151] and [0153]), meeting the limitation of claims 46 and 55. The instant claims do not define the patient population. The claims are drawn to a method of reducing the symptoms, not treating the disease. Therefore, anybody being administered the soluble Nogo-receptor polypeptide would necessarily have reduction in A $\beta$  peptide levels.

Therefore, the reference meets the limitation of claims 42-47, 49-50, 52-55 and 58-59.

The reference teaches that dosage regimens may be adjusted to provide the optimum desired response (e.g., a therapeutic or prophylactic response)...In some embodiments a therapeutically effective dose range for Nogo receptor-1 antibodies or antigen-binding fragments there of is 0.1-4 mg/kg per day (see paragraph [0140]). Please note, the reference teaches the nonelected species, instant SEQ ID NOS: 4, 5 and 6. The difference between the reference and the instant claims is that the reference does not teach that the therapeutically effective amount is from 1  $\mu$ g/kg to 10 mg/kg.

25. However, it would have been obvious to one of ordinary skill in the art to optimize the dosage range or concentration, according to the optimum desired response. One of ordinary skill in the art would have been motivated to do so and expect that optimum dosage range would at least provide better response. The MPEP states the following: Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges

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by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be *prima facie* obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 315 F.3d at 1330, 65 USPQ2d at 1382 (“*The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.*”); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.). For more recent cases applying this principle, see Merck & Co. Inc. v. Biocraft Laboratories Inc., 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989); *In re Kulling*, 897 F.2d 1147, 14 USPQ2d 1056 (Fed. Cir. 1990); and *In re Geisler*, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997). There is a motivation to optimize the dosage concentrations, since the normal desire of scientists or artisans want to improve upon what is already known, and the MPEP states that this *provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages*. There is a reasonable expectation of success, because routine optimization would at least arrive at the optimal dosage that is the most effective in treating the condition or disorders being treated. From the teachings of the

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reference, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention. Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

### ***Obviousness Double Patenting***

26. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

27. Claims 42-44, 47, 49-50, 52-53, 56 and 58-59 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 7-9 of U.S. Patent No. 7,465,705. Although the conflicting claims are not identical, they are not patentably distinct from each other because if one of ordinary skill in the art practiced the claimed invention of instant claims, one would necessarily achieve the claimed invention of U.S. Patent No. '705, and vice versa.

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28. Instant claims are drawn to a method for reducing the levels of A $\beta$  peptide in a mammalian brain, comprising administering a therapeutically effective amount of a soluble Nogo receptor-1 polypeptide, wherein the NgR1 comprises a peptide selected from the group consisting of SEQ ID NO: 3 (amino acids 26 to 310 of human NgR1).

The claims do not recite the patient population, therefore, administration of the polypeptide to anyone, *in vivo* and *in vitro* (brain cells) would necessarily reduce the levels of A $\beta$  peptide.

29. The claims of U.S. Patent '705 is drawn to an isolated soluble Nogo receptor-1 polypeptide comprising amino acids 26-310 of SEQ ID NO: 7, fused to immunoglobulin Fc. Claims 7-9 are drawn to a method for inhibiting growth cone collapse of a neuron, the inhibition of neurite outgrowth or neurite sprouting in a neuron, and promoting survival of a neuron at risk or dying, comprising contacting the neuron with the soluble Nogo receptor-1 polypeptide of claim 1. The patient population is not recited in these claims. The Nogo-receptor-1 polypeptide comprising amino acids 26-310 of SEQ ID NO: 7 is the same as the instant SEQ ID NO: 3.

30. Therefore, if one ordinary skill in the art practiced the instant claims, one would necessarily achieve the claimed invention of U.S. Patent No. '705, and vice versa, since the patient population is not defined. Therefore, if the polypeptide of instant claims is administered to anyone, any brain tissue, cells, one would necessarily achieve the claimed invention of U.S. Patent No. '705, and vice versa.

***Conclusion***

31. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE HA whose telephone number is (571)272-5982. The examiner can normally be reached on Mon-Thurs, 5:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Julie Ha/  
Examiner, Art Unit 1654